K033323

JAN 1 3 2004

510(k) SUMMARY

SUBMITTER:	Dideco S.p.A. 86, Via Statale 12 Nord 41037 Mirandola (MO) Italy
CONTACT PERSON:	Luigi Vecchi Phone: 011 39 0535 29811 Fax: 011 39 0535 25229
DATE PREPARED:	October 14, 2003
DEVICE TRADE NAME:	D 903 AVANT Adult Hollow Fiber Oxygenator (K980600) D 903 AVANT 2 Ph.I.S.I.O Adult Hollow Fiber Oxygenator with Ph.I.S.I.O coating (K020351)
COMMON NAME:	Hollow Fiber Oxygenator/Reservoir
CLASSIFICATION NAME:	Cardiopulmonary Bypass Oxygenator Cardiopulmonary Bypass Heat Exchanger Cardiopulmonary Bypass Blood Reservoir Cardiopulmonary Bypass Defoamer
PREDICATE DEVICES:	D 903 AVANT Adult Hollow Fiber Oxygenator (K980600) D 903 AVANT 2 Ph.I.S.I.O Adult Hollow Fiber Oxygenator with Ph.I.S.I.O coating (K020351) Monolyth Mimesys Adult Hollow Fiber Oxygenator (K004001)

DEVICE DESCRIPTION:

The D 903 AVANT and D 903 AVANT 2 Ph.I.S.I.O, hereafter referred to as the AVANT, are hollow fiber membrane oxygenators with integral heat exchanger and a hardshell cardiotomy/venous reservoir. The D 903 AVANT 2 Ph.I.S.I.O. is the phosphorylcholine coated version of the same AVANT oxygenator. The change covered by this submission is limited to extending the intended use of the AVANT (uncoated and coated versions) in order to allow the use of active venous drainage with vacuum. No modifications are being made to the devices themselves except an addition to the indications for use and instructions for use.

INDICATION FOR USE:

The previous indications for use has been modified as follows: "The Dideco D 903 AVANT Adult Hollow Fiber Oxygenator with Integral Hardshell Venous Reservoir is intended for use in adults who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation. It provides oxygenation and carbon dioxide removal from venous blood. The integrated heat exchanger provides blood temperature control and allows the use of hypothermia or aids in the maintenance of normothermia during surgery. The venous reservoir with cardiotomy filter is intended to collect blood aspirated from the operating field during surgical procedures and the blood from patient's veins (gravity or vacuum assisted) during normal operation to assure the proper oxygenation capability of the device. The device is intended to be used for six hours or less."

TECHNOLOGICAL CHARACTERISTICS:

The AVANT hollow fiber oxygenator is identical in design, operating principles, control mechanisms, manufacturing process and biocompatibility of the PmMI2 coating to the AVANT predicate devices. The only modification is the extension of the intended use of the AVANT (uncoated and coated version) to allow the use of active venous drainage with vacuum. The fundamental scientific technology of the modified device is not changed as a result of the extension of the intended use described in this submission.

The oxygenator is ethylene oxide sterilized and has a nonpyrogenic fluid path. It is for single use only.

BIOCOMPATIBILITY TEST RESULTS:

A complete battery of tests were carried out in accordance with the requirements of ISO 10993-1:1995 and the FDA May 1, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility testing on the raw materials. The AVANT was tested for Hemolysis, Cytotoxicity, Irritation, Acute Systemic Toxicity and Mutagenicity. Biocompatibility testing performed on AVANT and AVANT Ph.I.S.I.O. predicate devices have been taken as reference for the AVANT as the raw materials used in manufacturing process are identical to those used in the predicate devices. Sterility, Pyrogenicity, ETO residuals and package integrity testing were also conducted. The results of the testing met established specifications.

***IN VITRO* TEST RESULTS:**

In vitro testing were carried out in accordance with the requirements of "Guidance for Cardiopulmonary Bypass Oxygenators 510(k) submissions – Final Guidance for Industry and FDA Staff" issued on November 13, 2000 and when applicable, following the ISO 7199 (1996) standard for "Cardiovascular Implants and Artificial Organs – Extra Corporeal Blood-Gas Exchangers (Oxygenator)" for providing the data necessary to demonstrate both the substantial equivalence with the predicate device and also compliant with safety and effectiveness requirements. As the device is unchanged with respect to the predicate device safety and effectiveness characterization is based upon the performance characterization, physical characterization/integrity performed on AVANT (K980600) and AVANT Ph.I.S.I.O. (K020351) predicate device validation. Blood compatibility characterization and stability of the coating were performed on the AVANT Ph.I.S.I.O. predicate device (K020351). The device was aged up to 5 years (considered as worst case) and tested for hemolysis/cell depletion characterization, microembolic activity characterization, and reservoir housing integrity during active venous drainage. The results of these tests met established specifications.

The results of the study showed the device characteristics of the modified AVANT and predicate devices are comparable.

CONCLUSIONS:

The results of *in vitro* studies demonstrate that the AVANT Adult Hollow Fiber Membrane Oxygenator performs in a manner substantially equivalent to the predicate device. Biocompatibility studies demonstrate that the phosphorylcholine coating is biocompatible, and functional tests demonstrate that the AVANT is equivalent to the predicate devices, with respect to its intended use with vacuum drainage. Additional testing has demonstrated the effectiveness of production techniques to assure that the oxygenator is sterile and non-pyrogenic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 3 2004

Dideco S.P.A.
c/o Mr. Barry Sall
Parexel International Corp.
195 West Street
Waltham, MA 02451-1163

Re: K033323
D 908 AVANT Adult Hollow Fiber Oxygenator
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II (two)
Product Code: DTZ
Dated: October 14, 2003
Received: October 15, 2003

Dear Mr. Sall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K033323

Device Name: Dideco D 903 Avant Adult Hollow Fiber Oxygenator

Indications For Use:

The Dideco D 903 Avant Adult Hollow Fiber Oxygenator with Integral Hardshell Venous Reservoir is intended for use in adults who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation. It provides oxygenation and carbon dioxide removal from venous blood. The integrated heat exchanger provides blood temperature control and allows the use of hypothermia or aids in the maintenance of normothermia during surgery. The venous reservoir with cardiotomy filter is intended to collect blood aspirated from the operating field during surgical procedures and the blood from patient's veins (gravity or vacuum assisted) during normal operation to assure the proper oxygenation capability of the device. The device is intended to be used for six hours or less.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033323